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11 UNITED STATES OF AMERICA,

Plaintiff,

Defendant.

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v.

HUU TIEU,

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# UNITED STATES DISTRICT COURT

#### EASTERN DISTRICT OF CALIFORNIA

Case No. 1:20-cr-00109-ADA-BAM-1

MEMORANDUM ORDER FOLLOWING HEARING ON PRETRIAL VIOLATION PETITION, REVOKING RELEASE, AND REMANDING DEFENDANT INTO CUSTODY DURING PENDENCY OF ACTION

(ECF Nos. 60, 64)

I.

# **BACKGROUND**

On July 9, 2020, an indictment was filed charging Huu Tieu ("Defendant") with two counts of mail fraud in violation of 18 U.S.C. § 1341; three counts of introduction of misbranded drug into interstate commerce with the intent to defraud or mislead in violation of 21 U.S.C. §§ 331(a) and 333(a)(2); and seeking criminal forfeiture under 18 U.S.C. §§ 981(a)(1)(C), 982(a)(7), 21 U.S.C. § 334, and 28 U.S.C. § 2451(c). (ECF No. 1.)

Defendant made an initial appearance in custody on July 14, 2020, and pled not guilty. (ECF No. 4.) A detention hearing was held and Defendant was ordered released on his own recognizance with numerous pretrial services conditions stated on the record. (Id.) On the same date, an order setting conditions of release was issued. (ECF No. 6.) In part, Defendant was ordered to "not represent any Golden Sunrise product as having been approved or having 'proven

itself' to the FDA and must instruct all employees of Golden Sunrise Pharmaceutical, Golden Sunrise Nutraceutical, EDM Industries, Sylvia Harral, and Dr. Stephen Meis not to represent that any Golden Sunrise Product has been approved or has 'proven itself' to the FDA." (ECF No. 6 at 1-2.)

On May 30, 2023, a pretrial services violation petition was filed with an initial appearance on revocation proceedings set for June 7, 2023. (ECF No. 60.) The petition alleged that on May 26, 2023, the assigned government prosecutor notified pretrial services that Defendant had published a paper in December of 2022 describing ImunStem as being FDA approved, and that the assigned government prosecutor indicated he had confirmed with the FDA that ImunStem is not FDA approved and has never been FDA approved. (Id.)

On June 7, 2023, Defendant made an initial appearance on the pretrial release violation petition. (ECF No. 64.) Jeffrey Spivak appeared on behalf of the Government. John Garland appeared on behalf of the Defendant. Defendant was sworn and admitted the pretrial violation. The Government sought detention, and Defendant argued for release on conditions. The Court ordered Defendant detained, and denied the Defendant's request to self-surrender on June 8, 2023.

II.

#### LEGAL STANDARDS

The Bail Reform Act of 1984 ("Act"), 18 U.S.C. § 3141, *et seq.*, is the statutory scheme governing the circumstances under which bail may be granted as well as subsequently revoked. See, e.g., United States v. Wong, No. CR 12-00645 LEK, 2012 WL 5464178, at \*2 (D. Haw. Nov. 8, 2012). The Act mandates the pretrial release of individuals charged with a criminal offense if the Court can be reasonably assured that the defendant does not pose a flight risk or danger to the community. United States v. Damato, No. 2:20-MJ-00221-DJA-1, 2020 WL 2088100, at \*1 (D. Nev. Apr. 29, 2020) (citing 18 U.S.C. § 3142).

Section 3148 addresses the sanctions for violation of conditions of supervised release. "A person who has been released under section 3142 of this title, and who has violated a condition of his release, is subject to a revocation of release, an order of detention, and a

prosecution for contempt of court." 18 U.S.C. § 3148(a). Section 3148 further provides:

(b) Revocation of release.—The attorney for the Government may initiate a proceeding for revocation of an order of release by filing a motion with the district court. A judicial officer may issue a warrant for the arrest of a person charged with violating a condition of release, and the person shall be brought before a judicial officer in the district in which such person's arrest was ordered for a proceeding in accordance with this section. To the extent practicable, a person charged with violating the condition of release that such person not commit a Federal, State, or local crime during the period of release, shall be brought before the judicial officer who ordered the release and whose order is alleged to have been violated. The judicial officer shall enter an order of revocation and detention if, after a hearing, the judicial officer—

#### (1) finds that there is—

- (A) probable cause to believe that the person has committed a Federal, State, or local crime while on release; or
- **(B)** clear and convincing evidence that the person has violated any other condition of release; and

#### (2) finds that—

- (A) based on the factors set forth in section 3142(g) of this title, there is no condition or combination of conditions of release that will assure that the person will not flee or pose a danger to the safety of any other person or the community; or
- **(B)** the person is unlikely to abide by any condition or combination of conditions of release.

If there is probable cause to believe that, while on release, the person committed a Federal, State, or local felony, a rebuttable presumption arises that no condition or combination of conditions will assure that the person will not pose a danger to the safety of any other person or the community. If the judicial officer finds that there are conditions of release that will assure that the person will not flee or pose a danger to the safety of any other person or the community, and that the person will abide by such conditions, the judicial officer shall treat the person in accordance with the provisions of section 3142 of this title and may amend the conditions of release accordingly.

### 18 U.S.C. § 3148(b)(1)-(2).

Thus, "[r]evocation is governed by a two-step process." <u>United States v. Damato</u>, No. 2:20-MJ-00221-DJA-1, 2020 WL 2088100, at \*2 (D. Nev. Apr. 29, 2020). "At the first step, the Court must determine whether there is 'probable cause to believe that the person has committed

a Federal, State or local crime while on release,' *or* whether there is 'clear and convincing evidence that the person has violated any other condition of release.' " <u>Id.</u> (emphasis in original) (quoting 18 U.S.C. § 3148(b)(1)). The burden of proof at this step is on the government. <u>Id.</u> (citing <u>United States v. Petersen</u>, No. CRM 2008-0022, 2009 WL 1514402, at \*1 (D.V.I. May 29, 2009)).

"At the second step, the Court "shall" enter an order revoking pretrial release if it finds *either* that 'based on the factors set forth in section 3142(g) ... there is no condition or combination of conditions of release that will assure that the person will not flee or pose a danger to the safety of any other person or the community' *or* that 'the person is unlikely to abide by any condition or combination of conditions of release.' " <u>Damato</u>, 2020 WL 2088100, at \*2 (emphasis in original) (quoting 18 U.S.C. § 3148(b)(2)). "If the government establishes probable cause to believe the individual 'committed a Federal, State, or local felony' while on pretrial release, then 'a rebuttable presumption arises that no condition or combination of conditions will assure that the person will not pose a danger to the safety of any other person or the community.'

"Id. "Probable cause means only a 'fair probability,' not certainty, and requires consideration of the totality of the circumstances." <u>United States v. Krupa</u>, 658 F.3d 1174, 1177 (9th Cir. 2011) (citing <u>Illinois v. Gates</u>, 462 U.S. 213, 238 (1983)).

"However, if the rebuttable presumption does not apply, the statute is silent regarding the evidentiary standard that must be met by the government at the second step." See Damato, 2020 WL 2088100, at \*2 ("The Ninth Circuit has not addressed this issue."). This Court has previously found "[t]he determination of whether there is no condition or combination of conditions of release that will assure that Defendant will not flee or pose a danger to the safety of any other person or the community or that he is unlikely to abide by any condition or combination of conditions of release under section 3148(b)(2) may be established by a preponderance of the evidence." United States v. Patterson, No. 119CR00230DADBAM1, 2020 WL 6200164, at \*9 (E.D. Cal. Oct. 22, 2020) (citing United States v. Gotti, 794 F.2d 773, 778 (2d Cir. 1986); see also Damato, 2020 WL 2088100, at \*2 (noting "the Second Circuit has . . . [held] 'findings made under section 3148(b)(2) may be established by a by a preponderance of

the evidence[,]' " and that "[t]he analysis and rationale as to why the government's burden of proof is a preponderance of the evidence under § 3148 in <u>Gotti</u> is persuasive to this Court.").

III.

DISCUSSION

Again, pursuant to the order setting conditions of release issued on July 14, 2020, Defendant was ordered to "not represent any Golden Sunrise product as having been approved or having 'proven itself' to the FDA and must instruct all employees of Golden Sunrise Pharmaceutical, Golden Sunrise Nutraceutical, EDM Industries, Sylvia Harral, and Dr. Stephen Meis not to represent that any Golden Sunrise Product has been approved or has 'proven itself' to the FDA." (ECF No. 6 at 2.)

Initially, at the hearing held on June 7, 2023, there was no dispute by Defendant that Defendant violated this condition of pretrial release. Therefore, there was no contested hearing on the issue of whether the pretrial condition was violated, and the initial issue of whether there is "clear and convincing evidence that the person has violated any other condition of release," 18 U.S.C. § 3148(b)(1), was established by Defendant's waiver or admission of the issue. Accordingly, the parties focused their arguments on the question of whether there is no condition or combination of conditions of release that will assure that Defendant will not flee or pose a danger to the safety of any other person or the community, or whether he is unlikely to abide by any condition or combination of conditions of release. See 18 U.S.C. § 3148(b)(2).

In this regard, after admitting the violation, the Defendant argued he misinterpreted the condition of release. Defendant claims he interpreted the provision as restricting him from representing to the FDA that any Golden Sunrise products had been approved or proven, not that he was restricted from generally representing that a Golden Sunrise product was approved by the FDA. While Defendant is an immigrant from Vietnam, Defendant conceded he has very good English and writing skills. Here, Defendant proffered he has a history of contacting the FDA by email and telephone complaining about the fact the FDA had taken ImunStem down from a website that is accessible to doctors and pharmacists, and individuals at the FDA and other agencies had, because of these communications, labelled him as a vexatious complainer, and

prohibited him from contacting the FDA. Thus, essentially, Defendant argues because of that past history of contacting the FDA, he believed the provision was directed at preventing him from contacting the FDA and making such representations concerning the product to the FDA. Defendant also emphasized the amount of time that had elapsed from the time the conditions had originally been imposed, that he had complied with other conditions, and had no other violations.

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Taking the argument in the light most favorable to the Defendant, the Court concedes the condition could have been phrased a bit more clearly, perhaps with the addition of language such as follows: Defendant shall "not represent any Golden Sunrise product as having been approved [by] or having 'proven itself' to the FDA." (ECF No. 6 at 2 (alteration added).) However, based on the arguments presented at the hearing, the indictment in this case, the specific condition that was admitted to have been violated, and the published article at issue that was entered into the record, the Court finds the Defendant's proffered interpretation to be a wholly unreasonable interpretation of the condition of pretrial release, and the Defendant's proffered excuse is more of a post-hoc attempt to circumvent the condition, or decided to parse the phrasing before attempting to circumvent the condition. In this case, if the Court were to accept that as a premise, the Court would then be put in a position where it must find the Defendant is not in a position to comply with any conditions, as it appears Defendant is unable to comply with reasonable conditions tailored to the specific crimes he is in fact charged with. For the reasons stated below, the Court finds Defendant did understand the subject condition, utterly disregarded its parameters as tailored to the charged crimes, and the Court concludes Defendant would not be able to comply with any additional conditions the Court could impose.

The article in question entered into the record is entitled: "FDA Approves First Dietary Supplement under New Drug Application with the Indication of Serious or Life-Threatening Illnesses." The article was published in December of 2022, in Volume 13, Number 12, on the website entitled "Scientific Research," "[a]n Academic Publisher," available at https://www.scirp.org/journal/paperinformation.aspx?paperid=121936 (last accessed June 8, 2023). The articles authors are stated as: "Huu S. Tieu\*, Martin F. Loeffler Golden Sunrise Nutraceutical, Inc., Porterville, USA." The article states: "The novelty of ImunStem is that it is

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the first dietary supplement to be approved by the US Food and Drug Administration for Serious or Life-threatening conditions or diseases." The article purports that ImunStem aids the immune system in treating serious and life-threatening conditions:

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ImunStem can act alone safely or with other medical therapies to maximize efficacy and produce faster and lasting benefits to treat serious or life-threatening conditions or diseases by supporting immune system function. Physicians have observed that using ImunStem provokes a significant response, *i.e.*, a reduction in symptoms in patients with these diseases: autism, Alzheimer's, neuropathy, chronic lymphocytic leukemia, multiple sclerosis, Parkinson's, schizoaffective disorder, fragile-X syndrome, and a significant decrease of side-effects to chemotherapy for cancer. ImunStem has been shown to help reduce the loss of blood from surgical the wound and menstrual periods (shorter and lighter periods).

<u>Id.</u> As Defendant noted at the hearing, the article details some information about the FDA approval process, and proffered that his position in this case is that he believes the product *was* FDA approved, and has maintained that since arraignment, and in discussions with government agents. In this regard, the article states:

To sell any new drug/medicine in the United State of America, Golden Sunrise Nutraceutical, Inc. (Golden Sunrise) must comply with the FDA under 21U.S.C. §355(a) [16]. ImunStem product with an NDA No.: 204701 must contain complete medical report results and an Investigator's Brochure about the drug/medicine, safety, effectiveness, the composition including drug/medicine, description of how the drug is manufactured, and proposed labeling under 21U.S.C. §355(b) [16]. The first time Golden Sunrise applied with FDA (form 356h) was on January 07, 2013 under 21U.S.C. §355(j) [16], then it was filed with the Antiviral division; on November 05, 2018. The second application was submitted to FDA Regenerative Medicine Advanced Therapy (RMAT) division. The third application was submitted to the Coronavirus Treatment Acceleration Program (CTAP) division on April 03, 2020, and on April 05, 2020, FDA CTAP assigned TRIAGED and Submission Tracking No.: 435. The FDA had approved ImunStem NDA No.: 204701 under the Accelerated Approval Program by regulations governing under 21C.F.R. FDA-2013-D-0575 [17]. Traditional approval requires that clinical benefits be shown before approval can be granted. Accelerated approval is given to some new drugs for serious or life-threatening illnesses that lack satisfactory treatments. This allows an NDA to be approved before measures of effectiveness that would usually be required for approval are available [18]. On July 02, 2018, ImunStem received from FDA NDC Directory No.: 70642-001-01 Human Prescription Drug [19]. FDA agreed to Priority Review designation for ImunStem product with the notification of the New

Drug Application on January 07, 2013 [20].

<u>Id.</u>

The Court must reject the Defendant's arguments. Turning to the indictment for example, it states: "Beginning at least on or about March 23, 2020, TIEU caused false statements to be made to members of the media, to potential customers of Golden Sunrise, and to the general public that Golden Sunrise products were FDA approved . . . " (ECF No. 1 at 5-6.) The indictment also indicates that an FDA inspector conducted an on-site inspection of Golden Sunrise in 2019, and "he addressed, with TIEU, the false claim on a website TIEU managed, ImunStem.com, that ImunStem was FDA approved, leading TIEU to remove the claim from the website." (ECF No. 1 at 8.) The Court finds it significant that looking to conduct that is the subject of the violation admission, and the nature of the indictment, the conduct is essentially a major component underlying the indictment itself

The Court considers whether Defendant is unlikely to abide by any condition or combination of conditions of release. 18 U.S.C. § 3148(b)(2). Based on a review of the article, particularly the heading, the paper proceeds to speak to examples of patient testimonials of various diseases, many life-threatening, and appears to give analysis by way of a first person perspective under the guise the FDA approval. The Court finds Defendant absolutely knew what he was not supposed to do, clearly violated the condition of release (as conceded), and if he actually didn't know or understand the term of the condition, given the tenor of the indictment in relation to the article, the Court would find the Defendant unable to abide by his terms and conditions, as apparent by these actions.

The Court also considers whether there is no condition or combination of conditions of release that will assure that Defendant will not flee or pose a danger to the safety of any other person or the community. See 18 U.S.C. § 3148(b)(2). Here, to target people with serious or life-threatening medical conditions, with a foreseeable result that people in their position will take medication with the sense of hope that pain or life-threatening conditions will be alleviated, presents a clear danger to society, and could result in harm or death for individuals. The Court therefore finds that to be a danger to persons in the community, and the disregard of the laws and

the restrictions the Court has imposed, demonstrates there is no condition or combination of conditions that would assure the safety of community.

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Additionally, even aside from direct physical danger that may result from individuals utilizing treatments on the false belief they are FDA approved to treat their disease, the individuals, and indeed their family members, in desperate medical situations and facing potential death, are prone to significant economic harm when in such a vulnerable position. In this regard, the Bail Reform Act sets forth the specific types of criminal charges that initially qualify a defendant for pretrial detention as a serious or substantial risk of danger to other persons or the community. 18 U.S.C. § 3142(f)(1)(A)-(E). "'Economic crimes' such as mortgage or financial fraud do not qualify as such offenses." United States v. Soria, No. 2:11-CR-00156-LDG, 2011 WL 3651272, at \*5 (D. Nev. Aug. 17, 2011) (citing <u>United States v.</u> Giordano, 370 F.Supp.2d 1256, 1261-62 (S.D. Fla. 2005); United States v. Himler, 797 F.2d 156, 160 (3rd Cir. 1986); <u>United States v. Byrd</u>, 69 F.2d 106, 109–10 (5th Cir. 1992); <u>United</u> States v. Ploof, 851 F.2d 7, 11 (1st Cir. 1988)). However, "[w]hile economic crimes will not ordinarily trigger the danger to the community analysis in initial detention hearings, 'in postinitial detention proceedings, the Ninth Circuit has unequivocally ruled that economic harm may be considered as a justification for detaining someone as a danger to the community." . Patterson, 2020 WL 6200164, at \*10 (quoting United States v. Gill, No. CR S-06-0312LKK(GGH), 2008 WL 2120069, at \*3 (E.D. Cal. May 20, 2008)) (citing <u>United States v.</u> Reynolds, 956 F.2d 192, 192 (9th Cir. 1992)); see also United States v. Slade, No. CR-09-1492-1-PHX-ROS, 2013 WL 2455926, at \*6 (D. Ariz. June 5, 2013) ("Courts have long recognized that 'danger' in the context of § 3148 refers to unlawful conduct, with little distinction between whether the nature of the conduct is economic or physical." (quoting Wong, 2012 WL 5464178, at \*2)).

For all of the above reasons, the Court finds the preponderance of the evidence establishes there is no condition or combination of conditions of release that will assure that Defendant will not flee or pose a danger to the safety of any other person or the community or that he is unlikely to abide by any condition or combination of conditions of release. 18 U.S.C. §

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1	3148(b)(2); Patterson, 2020 WL 6200164, at *9; Damato, 2020 WL 2088100, at *2.
2	Accordingly, Defendant's pretrial release shall be revoked. 18 U.S.C. § 3148(a).
3	IV.
4	ORDER
5	Based on the foregoing, IT IS HEREBY ORDERED that:
6	1. Defendant Huu Tieu's pretrial release is REVOKED;
7	2. Defendant Huu Tieu shall be detained during the pendency of this case; and
8	3. Defendant Huu Tieu shall appear before District Judge Ana de Alba for a trial
9	confirmation hearing on February 5, 2024, at 8:30 a.m., in Courtroom 1.
10	IT IS SO ORDERED.
11	Theref A. De
12	Dated: June 8, 2023 UNITED STATES MAGISTRATE JUDGE
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